

**Notice of Allowability**

Application No.

10/085,234

Applicant(s)

CHOPRA, SHAM

Examiner

Art Unit

James M. Spear

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to The Amendment filed 10 January 2005.
2. ☒ The allowed claim(s) is/are 1-5, 7-11, 21-24, 26-30, 36-39, 43-45 and 51.
3. ☒ The drawings filed on 28 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 3-17-05
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER

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HC

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick H. Higgins on 18 March 2005.

IN THE CLAIMS:

Claims 11, 30 and 45. In the line next to the last line of each claim delete the words –alternative or-

Claim 30, line 1 after based, insert, on

Claim 38, line 1 after 37, delete, herein, insert, wherein

Claim 45, last line after thereof add a period.

1. The following is an examiner's statement of reasons for allowance:
2. Applicants show a dissolution controlled chemical delivery device for controlled release of an active ingredient. Conte et al US 5,422,123, considered the closest prior art of record, shows a dosage form comprised

of a core and a support platform wherein release of the active agent results from polymer substances that are slowly soluble and/or slowly gellable in aqueous liquid. The prior art does not show nor fairly suggest applicants' dissolution device that maintains structural integrity in an aqueous environment comprised of an active ingredient core surrounded by a distinct coating comprised of an insoluble polymer selected from the group consisting of ethylcellulose, cellulose acetate, cellulose acetate butyrate, polyvinyl alcohol, polyvinyl acetate, and methacrylic acid copolymer and at least one ph sensitive polymer selected from the group consisting of cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, polyvinylacetate phthalate and polymethacrylate. The particular insoluble polymer and ph sensitive polymer combination provides a rigid coating that maintains its dimensions wherein the release rate of the active ingredient is determined by surface area and rate of dissolution from said core.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 1-5, 7-11, 21-24, 26-30, 36-39, 43-45 and 51 are allowed.

Claims 6, 12-20, 25, 31-35, 40-42, 46-50 and 52-64 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

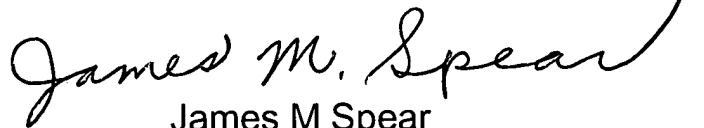
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

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access to the Private PAIR system, contact the Electronic Business Center  
(EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "James M. Spear". The signature is written in a cursive style with a large, sweeping flourish at the end.

James M Spear  
Primary Examiner  
Art Unit 1615

March 17, 2005